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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/214,478 | 06/07/1999 | PHILIP E BRANTON | 50013/002003 | 8679 |

21559 7590 07/28/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

CHEN, SHIN LIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 07/28/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.



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KRISTINA BIEKER BRADY
CLARK & ELBING
176 FEDERAL STREET
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RESTARZ

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Office Action Summary

Application No.

09/214,478

Applicant(s)

Branton et al.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 11, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81, 85-88, 92, 93, 95, 99, and 100 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81 and 85-87 is/are allowed: allowable.
- 6) ☒ Claim(s) 88, 92, 93, 95, 99, and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicants' amendment filed 3-11-03 has been entered. Claims 61-63 have been canceled. Claims 88 and 95 have been amended. Claims 81, 85-88, 92, 93, 95, 99 and 100 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 88, 92, 93, 95, 99 and 100 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 3-11-03 necessitates this new ground of rejection.

The phrase "and wherein E4 polypeptides other than said E4orf4 polypeptide are not expressed by said vector" in the amended claims 88 and 95 is considered new matter. The added material is not supported by the original disclosure. The specification only provides description for E4orfs, under the control of CMV promoter, individually cloned into pCDNA3.1 plasmid and Figs 11 and 12 show adenovirus Ad5 produces E4orf4 and E4orf6 proteins. The specification fails to provide sufficient description that E4 polypeptides other than E4orf4 are not expressed in

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a vector. There is no nexus between cloning E4orfs individually into a plasmid and E4 polypeptides other than E4orf4 are not expressed in a vector. Cloning E4orfs individually into a plasmid does not necessarily mean that E4 polypeptides other than E4orf4 are not expressed in a vector. Further, Figs 11 and 12 fail to show that E4 polypeptides other than E4orf4 are not expressed in a vector. In fact, Figure 11 does show coexpression of E4orf4 and E4orf6 (dI 1013 (orf 4+ 6). Thus, the phrase "and wherein E4 polypeptides other than said E4orf4 polypeptide are not expressed by said vector" in the amended claims 88 and 95 is considered new matter. Claims 92 and 93 depend on claim 88 and claims 99 and 100 depend on claim 95.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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4. Claims 88, 92, 93, 95, 99 and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaplan et al., (US Patent No. 6,100,086). Applicants' amendment filed 3-11-03 necessitates this new ground of rejection.

Claims 88, 92, 93, 95, 99 and 100 are directed to an expression vector comprising nucleic acid sequence encoding SEQ ID No. 4 (E4orf4) and capable of inducing apoptosis, wherein said nucleic acid is operably linked to a heterologous inducible, constitutive, or cell-type specific regulatory sequence and E4 polypeptides other than E4orf4 are not expressed in a vector, and a pharmaceutical composition comprising said expression vector and a pharmaceutically acceptable carrier. Claims 93 and 100 specify the nucleic acid is an adenoviral vector or a retroviral vector.

Kaplan teaches construction of an Ad2 vector by inserting a transgene into the Ad2- β gal-7 vector after removing the beta-galactosidase gene to form Ad2 vector with an E4orf4 E4 region (Ad2/ β gal7 (E4orf4)). "The E4 cassette is preferably provided on a single vector although individual ORFs of the E4 cassettes may be provided on separate vectors as needed. The E4 cassette... may be placed under the control of heterologous promoters such as CMV" (column 11, lines 13-33, example 5). Kaplan teaches Ad2 vectors comprising one or more E4orfs can be made by recombinant DNA method, such as PCR amplification (bridging column 17-18). The buffer solution containing the Ad2/ β gal7 (E4orf4) vector is considered a pharmaceutically acceptable carrier. Thus, claims 88, 92, 93, 95, 99 and 100 are anticipated by Kaplan.

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Conclusion

Claims 88, 92, 93, 95, 99 and 100 are rejected. Claims 81 and 85-87 are in condition for allowance.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Shin-Lin Chen, Ph.D.